

“One of the strengths of our business model is the quality of the pharmaceutical companies with whom we collaborate,” said Richard Pops, Chief Executive Officer of Alkermes. “Johnson & Johnson is one of the world’s leading health care companies. We have great confidence in relying on their ability and judgment in dealing with regulatory authorities around the world.”

Risperdal Consta is a long-acting injectable formulation of Risperdal® that uses Alkermes’ Medisorb® drug-delivery technology. If approved, Risperdal Consta will be manufactured by Alkermes and the product will be marketed by Janssen Pharmaceutica Products, L.P. in the United States, Janssen-Ortho in Canada and Janssen-Cilag elsewhere.

77. Similarly, on July 1, 2002, Alkermes’ joint venture partner, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., issued a press release entitled “Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Receives Non-Approvable Letter for RISPERDAL® CONSTA™.” The press release said in part:

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), today announced that it has received a non-approvable letter from the U.S. Food and Drug Administration (FDA) related to its New Drug Application (NDA) for RISPERDAL® CONSTA™ (risperidone) long-acting injection. Issued at the 10-month goal FDA has set for responding to standard NDAs, the letter invited further dialogue with the agency to resolve questions regarding certain aspects of the pre-clinical data. No significant concerns were raised regarding the manufacturing process.

“We believe we will be able to satisfactorily resolve the FDA’s questions about the pre-clinical data,” said Harlan Weisman, M.D., executive vice president of research and development at J&JPRD. “We look forward to doing so in an expeditious manner and moving ahead with the approval process.”

RISPERDAL® CONSTA™ is a long-acting injectable formulation of RISPERDAL® that uses Alkermes’ proprietary, injectable, extended-release, drug-delivery technology, Medisorb®.

The technology is based on the encapsulation of drugs into small polymeric microspheres that degrade slowly and release the medication at a controlled rate following subcutaneous or intramuscular injection. If it is approved, RISPERDAL® CONSTA™ will be manufactured by Alkermes and marketed in the United States by Janssen Pharmaceutica Products, L.P.

“We believe RISPERDAL® CONSTA™ will represent an important new treatment option for persons with schizophrenia by offering all of the benefits of an atypical antipsychotic in a long-acting form,” Dr. Weisman continued. “It has been estimated that as few as 25 percent of persons with schizophrenia take their medication on a consistent basis – a problem that can lead to relapse and re-hospitalization. Because of its two-week duration of effect, thus eliminating the need for daily pills, RISPERDAL® CONSTA™ may help increase adherence to treatment.”

78. Together, the disclosures of July 1, 2002, point to unresolved medical issues, such as those relating to safety and efficacy of the Risperdal Consta drug product. While the Johnson & Johnson disclosure indicated that there were no significant issues presented regarding the manufacturing process, Defendants failed to note in their press release that they were still unable to begin commercial manufacture of the product for the U.S. markets at the expected levels. While at a very late stage of the NDA process, for a product that allegedly presented no significant issues regarding the manufacturing process itself, Defendants were still at the earliest stage of refocusing their Wilmington research and development operations into an elaborate, highly automated commercial manufacturing facility, with plans to begin validation activities *at the end of the third quarter 2002*. Thus, despite assurance of no significant manufacturing process issues in the July 1, 2002 Johnson & Johnson press release, the Wilmington facilities were in fact still wholly unable to begin commercial manufacture of the product for the U.S. markets at the expected levels.

79. As a result of Defendants' announcement of the non-approvable letter for Risperdal Consta on July 1, 2002, Alkermes' stock price dropped precipitously over the two-day period following the announcement, from a high of \$16.01 to a low of \$4.04, or a drop of 74.8%, on total volume of 29 million shares.

### **POST CLASS PERIOD REVELATIONS**

#### **Failed Merger**

80. On August 14, 2002, Reliant Pharmaceuticals terminated its merger agreement with Alkermes. While Defendants had expected to consummate the transaction based on the overly inflated value of the Company's stock, they could not control the timing of the FDA's issuance of a rejection letter for Risperdal Consta.

#### **Stroke and Death in the Elderly**

81. On October 17, 2002, the Health Products and Food Branch of Health Canada issued the following notice to healthcare professionals, entitled "Updated Safety Information for Risperdal (Risperidone) in Elderly Dementia Patients, Announced in Canada":

Further to discussions with Health Canada, Janssen-Ortho Inc. advised healthcare professionals of new safety information for the use of RISPERDAL (risperidone), an antipsychotic medication in elderly, dementia patients. The manufacturer has notified doctors and pharmacists of reports of strokes and stroke-like events in clinical studies in elderly patients with dementia taking RISPERDAL.

Data were analyzed from four clinical studies in elderly, dementia patients. In two of these studies, a higher proportion of patients taking RISPERDAL experienced strokes or related events than did those who received placebo (sugar pill). Further information from ongoing analyses of clinical studies will be posted as it becomes available.

Worldwide exposure to RISPERDAL in elderly, dementia patients is approximately 2.5 million patient years. From this patient population, there have been 37 reports of strokes or stroke-like events (1 in Canada), including 16 deaths (1 in Canada). Generally, there is an increased risk of strokes and stroke-like events in the elderly population.

Patients or their caregivers should immediately report to their doctors any signs and symptoms of potential strokes such as sudden weakness or numbness in the face, arms or legs, and speech or vision problems. Patients or their caregivers should inform their doctors of their past and present medical history, including history of stroke or stroke-like events, and should also consult their doctor prior to making any changes in their medication.

Information about this safety update has been sent to doctors and pharmacists to ensure that they are aware of this new safety information when prescribing and dispensing RISPERDAL. The company is working with Health Canada to update the Canadian prescribing information for RISPERDAL. In the interim, all healthcare professionals are advised to review the healthcare professional letter.

82. The CVAE results of certain clinical studies cited by Health Canada were not discussed in the Risk Assessment article of September 2000, nor were they addressed in the July 1, 2002 disclosures. Despite these omissions, the CVAEs of Risperdal were considered to be so serious that, once discovered by regulatory authorities, warnings were required by Canadian and U.S. authorities to protect the health and welfare of elderly patients taking Risperdal. Defendants knew but concealed the fact that this warning would have a serious negative impact on the market for and approvability of Risperdal Consta, since Defendants knew it would be impossible to discontinue or withdraw, once administered, a deep intramuscular injection of the Risperdal Consta biweekly dosage form in the event that signs and symptoms of potential CVAEs were reported by elderly patients.

### **Tardive Dyskinesia**

83. The Risk Assessment article of September 2000 also noted a single case of de novo tardive dyskinesia in a clinical study involving 413 patients. The August 9, 2002 U.K. product approval press release failed to note the potential for tardive dyskinesia side effects while using Risperdal Consta. A warning for tardive dyskinesia appearing on the U.S. package insert for oral and liquid dosage forms of Risperdal since 1999 provides a recommendation that withdrawal of the Risperdal drug therapy be considered should the symptoms of tardive dyskinesia appear. In such circumstances, the alternative use of Zyprexa or Clozaril has been reported. Tardive dyskinesia, a known Risperidone-induced side effect, is a syndrome marked by involuntary movement of the lips or jaw and certain other dystonic gestures. Defendants knew but concealed the fact that if tardive dyskinesia was observed by a patient who was prescribed Risperdal Consta, it would be impossible for a healthcare provider to comply with the recommendation indicated on an approved U.S. package insert for current Risperdal dosage forms, to withdraw, once administered, a deep intramuscular injection of the Risperdal Consta biweekly dosage from patients afflicted with the drug-induced syndrome.

#### **Extrapyramidal Symptoms**

84. The Defendants produced all clinical trial supplies used in clinical studies reported in the article entitled "The First Antipsychotic of the 2nd Generation in a Depot Form: Risperidone Microspheres in Intramuscular Injections," published in the *Journal Psychiatrie* ("Psychiatrie Paper") during the second half of 2002. The paper is summarized as follows:

#### **Summary**

Risperidone is the first antipsychotic of the 2nd generation that is distributed in depot injections. Intramuscular application leads to therapeutic plasma levels within 3-4 weeks – this is also the period for which risperidone has to be simultaneously administered perorally in the beginning of treatment. The depot injections reach steady-state plasma concentrations without major fluctuation or high peaks of maximum levels following the application.

Risperidone in the depot form was tested in five 3-4 month trials, 3 of which were open and 2 double-blind, and in a single long-term, 50-week study, in which the total of 1892 patients treated for schizophrenic and schizoaffective disorders were involved. Risperidone depot injections were more effective than placebo and equally effective as the oral form of the same drug in influencing not only the positive, but also the negative and affective symptoms and in normalising the scores of the quality-of-life scale. 17.6 % of patients were rehospitalised during the one-year treatment and the length of inpatient treatment was significantly shorter.

***The most frequent side-effects included extrapyramidal reactions observed in 20-30 % of patients depending on the application dose, hyperprolactinemia, mild weight gain, and in 10-15 % of patients also headache, somnolence and dyspepsia.***

Risperidone in the depot form is a preferential choice for maintenance therapy of patients with schizophrenic and schizoaffective disorders who refuse oral administration of drugs or repeatedly discontinue therapy.

85. Extrapyramidal symptoms or EPS are characterized by stiffness, rigidity, uncontrollable tremors, involuntary movements, restlessness and other symptoms and are a serious problem associated with antipsychotic medications. ***EPS are believed to have a major impact on patient compliance, especially for the majority of schizophrenia patients who are on long-term treatment.*** Defendants knew but concealed the fact that, paradoxically, the use of the Medisorb sustained-release delivery system with Risperdal ***almost doubles*** the occurrence of EPS, ***while***

*actually making it impossible for afflicted patients to discontinue treatment*, since it would be impossible to discontinue or withdraw, once administered, a deep intramuscular injection of the Risperdal Consta biweekly dosage form in the event EPS arise.

86. The FDA-approved U.S. package insert indicates that EPS is an adverse event experienced with the use of Risperdal oral formulations. As many as 3.8% of patients treated with Risperdal discontinued use because of extrapyramidal symptoms in controlled clinical trials. Notably, the statement of the author of the Psychiatric Paper actually belies the safety-based limitations on the marketability of Risperdal Consta by adopting a position that forces the use of the depot form of the drug on those patients who refuse Risperdal, *when extrapyramidal symptoms would cause them to refuse Risperdal therapy*:

Risperidone in the depot form is a preferential choice for maintenance therapy of patients with schizophrenic and schizoaffective disorders who refuse oral administration of drugs or repeatedly discontinue therapy.

87. The results reported in the Psychiatric Paper, of clinical studies necessary for product registration activities, point to the concealment by Defendants during the Class Period of the facts relating to known clinical experience with Risperdal side effects that would have an exceptional impact on the marketability of the drug, including *(i) whether or not Risperdal Consta can be safely given to patients absent prior patient experience with the drug; (ii) whether or not a period of safe use with oral formulations of Risperdal must be established prior to administration of Risperdal Consta; and (iii) whether or not these issues stood in the way of the successful achievement of Defendants' product revenue and profitability goals.*



88. The lowest ex-US dosage form of Risperdal Consta currently available, 25 mg, is equivalent to a 2 mg daily oral dosage. The FDA-approved U.S. package insert summarizes data demonstrating the dose-relatedness for the triggering of extrapyramidal symptoms associated with Risperdal treatment. Thus, a higher prescribed dose of Risperdal or an inadvertent acute overdose of Risperdal can trigger EPS. Defendants also knew, based on the FDA-approved U.S. package insert that the enzyme responsible for metabolism of risperidone to 9-hydroxy-risperidone is actually a family of polymorphic enzymes capable of wide variation in metabolic rates by race and that no definitive pharmacokinetic studies looking at differences in dosage requirements by race and gender have been performed for Risperdal. Defendants knew but concealed the fact that EPS would be an even more serious side effect for a depot form of Risperdal, by collaborating with its joint venture partner in the overseas marketing of the drug with the following warning in the event of “overdose,” provided for in the U.K.-registered package insert for Risperdal Consta:

Symptoms:

In general, reported signs and symptoms have been those resulting from an exaggeration of the drug’s known pharmacological effects. These include drowsiness and sedation, tachycardia and hypotension, and extrapyramidal symptoms. In overdose, rare cases of QT-prolongation have been reported. In case of acute overdosage, the possibility of multiple drug involvement should be considered.

Treatment:

Establish and maintain a clear airway, and ensure adequate oxygenation and ventilation. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias.



There is no specific antidote to Risperdal. Therefore appropriate supportive measures should be instituted. Hypotension and circulatory collapse should be treated with appropriate measures such as intravenous fluids and/or sympathomimetic agents. In case of severe extrapyramidal symptoms, anticholinergic medication should be administered. Close medical supervision and monitoring should continue until the patient recovers.

### **Arrhythmia and Sudden Death**

89. Torsades de Pointes is a syndrome of polymorphic ventricular tachycardia occurring in the setting of marked prolongation of the electrocardiographic QT interval. It occurs in individuals genetically predisposed to the disorder and is a frequent cause of sudden death in these individuals. Defendants knew that adverse pro-arrhythmic effects linked to QT interval prolongation were of concern to the FDA and that as many as 40 marketed drugs, including Risperdal and a similar number of drugs under development have been found to prolong the QT interval. Drug induced Torsades de Pointes is a relatively rare event but can be as high as 2% to 3% with some drugs.

90. Defendants noted instances of tachycardia (rapid heart beat) in their press release of August 9, 2002, but failed to address how Risperdal Consta patients experiencing QT interval prolongation would be treated. Defendants were aware of the February 7, 2002 draft guidance entitled "Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals." This guidance concludes that, while recognizing that clinical data related to the measurement of QT interval prolongation is important, efforts must also focus on nonclinical and preclinical aspects predictive of the condition. Despite this knowledge, Defendants concealed the fact that if QT interval prolongation would be experienced by a patient who was prescribed Risperdal Consta, it would be impossible for a healthcare provider to discontinue

treatment, since it is impossible to withdraw, once administered, a deep intramuscular injection of the Risperdal Consta biweekly dosage from patients afflicted with QT interval prolongation.

### **Drug-Drug Interactions**

91. Drug-drug interactions are also an important safety concern. These interactions can occur when two or more drugs interact with each other. It is generally known that the need to administer selective serotonin uptake inhibitors such as Zoloft or Prozac can slow the metabolism of Risperdal, resulting in Parkinson-like symptoms. Defendants concealed the fact that, in contrast to oral dosage forms, it would be impossible for a healthcare provider to immediately withdraw a deep intramuscular injection of the Risperdal Consta dosage form, even if the patient is faced with therapeutic needs and requirements incompatible with Risperdal therapy.

### **Diabetes: Risperdal Not An Exception**

92. On Monday, August 25, 2003, Erica Goode, a human behaviour staff writer for *The New York Times* ("NYT"), authored the following newspaper article in the NYT regarding the risk of diabetes resulting from the use of Risperdal, entitled "3 Schizophrenia Drugs May Raise Diabetes Risk, Study Says." The article stated in part:

Three drugs commonly prescribed for schizophrenia and other psychotic illnesses increased patients' risk of developing diabetes when compared with older antipsychotic medications, researchers said yesterday, presenting the results from a long-awaited study of patients treated at veterans hospitals and clinics across the country.

The drugs – Zyprexa, made by Eli Lilly, Risperdal, made by Janssen Pharmaceutica, and Seroquel, made by AstraZeneca – were associated with higher rates of diabetes than older generation drugs for schizophrenia like Haldol, the study found. But the increased risk was statistically significant only for Zyprexa and Risperdal, the researchers

said, possibly because of the smaller number of subjects in the study who took Seroquel.

***Younger patients, under age 54, who took Zyprexa or Risperdal showed the highest risk of developing diabetes, the study,*** led by Francesca Cunningham of the Department of Veterans Affairs at the University of Illinois at Chicago, found.

The results add to a growing number of reports linking Type 2 diabetes to some drugs in the class of antipsychotics known as atypicals.

***“These findings are absolutely consistent with everything we’ve looked at and seen,” said Robert Rosenheck, a professor of psychiatry and public health at Yale and an author of an earlier study that found an increased risk of diabetes with Zyprexa, Risperdal, Seroquel and Clozaril, made by Novartis.***

***Experts said the new findings underscored the need for patients who take the drugs and doctors who prescribe them to be alert for the symptoms of diabetes, including increased thirst, frequent urination, increased appetite or rapid weight gain.***

Atypical antipsychotics, studies indicate, are less likely than older drugs to produce side effects like tardive dyskinesia, a devastating movement disorder. The newer drugs also appear more effective in preventing relapse in patients with schizophrenia and may be more effective in treating certain aspects of the illness.

More than 15 million prescriptions were written last year for Zyprexa and Risperdal, the two leading atypical antipsychotics, according to industry figures.

Researchers in the last two years have found higher rates of diabetes and hyperglycemia, medical conditions that are usually reversible, among patients taking the newer drugs. But many of the studies have been based on case reports in medical journals or filed voluntarily by doctors with the Food and Drug Administration, making it difficult to determine the size of the problem or whether it is associated with particular drugs or with the class of drugs as a whole.

The new study, scientists said, is important because of its careful methodology and substantial size: the researchers based their analyses on medical records from 19,878 veterans treated with an older or newer drug between October 1998 and October 2001.

Of 5,981 veterans who took Zyprexa, 200, or 3.34 percent, developed diabetes, compared with 170, or 2.43 percent, of 7,009 veterans taking Haldol or another older medication. Of 5,901 patients taking Risperdal, 193, or 3.27 percent, developed diabetes; 21, or 2.39 percent, of 877 veterans taking Seroquel developed the illness. All three drugs raised a patient's chances of developing the illness by about 50 percent, but the meaning of the increased risk among patients taking Seroquel was unclear because of the smaller number of subjects who took the drug, the researchers said.

"We need a larger number of observations to be certain what its risk is and whether it differs from other drugs," said Bruce Lambert, an associate professor of pharmacy administration at the University of Illinois at Chicago and an author of the study.

The study was financed in part by Bristol Myers Squibb, the maker of Abilify, an atypical that had not entered the market when the study began and has not been systematically studied for a link to diabetes.

\* \* \*

Laura Bradbard, a spokeswoman for the F.D.A., which has been tracking the diabetes issue, said the agency was reviewing the new findings, which were presented yesterday in Philadelphia at a meeting of the International Society for Pharmacoepidemiology . . . .

The agency is considering whether to add or strengthen warnings in the labeling of certain drugs or on the class of drugs as a whole.

How atypical antipsychotics might produce or uncover diabetes is unknown. Weight gain, a side effect of some drugs, may play a significant role, researchers believe. But P. Murali Doraiswamy, chief of the division of biological psychiatry at Duke University, said that in

some cases the illness has come on rapidly, before patients have time to gain weight.

93. Despite earlier public assurances that Risperdal was found to be an exception to the increased risk of diabetes posed by certain atypical antipsychotics, Defendants sought to conceal the serious negative impact on the market for and approvability of Risperdal Consta that would inevitably follow a link to diabetes.

94. The true facts, which were known by each of the Defendants during the Class Period but were concealed from the investing public, were as follows:

(a) In an attempt to decrease development expenses and speed the product to market, Defendants concealed the deficient nature of the manufacturing process for Medisorb PLGA polymer used to manufacture Risperdal Consta, resulting in quality management issues and delays in the development program;

(b) In order to conceal lot-to-lot variations resulting from the manufacturing process for Medisorb polymer manufacture, Defendants minimized process development and validation requirements, including the establishment of specifications and analytical tests necessary to control those variations;

(c) Significant quality issues for the manufacture of Risperdal Consta existed at the Wilmington, Ohio facilities, impacting the ability of the Company to meet clinical development timelines for Risperdal Consta;

(d) In order to avoid disclosure of the serious deficiencies of the Medisorb manufacturing process, particularly the lot-to-lot variation in molecular weight for Medisorb polymer,

and in order to find a way to fix the desired molecular weight of the Risperdal Consta finished drug product, Defendants patented a method to degrade the finished product to the desired molecular weight;

(e) Defendants' revenue projections for Risperdal Consta were grossly inflated based on Defendants' concealment of the fact that Risperdal's adverse effects and safety or tolerability issues are worsened when Risperdal is formulated using Medisorb technology and used as intended;

(f) Defendants concealed the combined effect of the financial agreements reached with its joint venture partner, Janssen, that Risperdal Consta would not be profitable unless it achieved the high end of sales projections, an unlikely outcome because of the worsening of Risperdal's adverse effects and safety or tolerability issues when the drug was formulated using Medisorb technology and used as intended;

(g) The serious safety concerns for Risperdal "oral" and Risperdal Consta "depot" products, such as CVAEs in elderly patients, extrapyramidal symptoms, QT interval prolongation and diabetes, which were detected in clinical trials that went unreported to worldwide regulatory authorities for long periods, in some cases for studies completed well before the beginning of the Class Period, were negatively impacting the regulatory review process;

(h) For one or more reasons related to the known but unmet manufacturing, safety or efficacy requirements for the drug, the NDA for Risperdal Consta would not be approved on July 1, 2002; and

(i) The failure to disclose the defective nature of the Risperdal Consta chemical and manufacturing controls, clinical program, safety and other issues preventing the Company from

realizing product approval would prevent investors from learning the extent of the misrepresentations made to them during the Class Period.

### **FRAUDULENT SCHEME AND COURSE OF BUSINESS**

95. The market for Alkermes' securities was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and failures to disclose, Alkermes' common stock traded at artificially inflated prices during the Class Period. Plaintiff and the other members of the Class purchased or otherwise acquired Alkermes securities relying upon the integrity of the market price of Alkermes' securities and market information relating to Alkermes, and have been damaged thereby.

96. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Alkermes' common stock, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make Defendants statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

97. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and the other members of the Class. As described herein, during the Class Period Defendant made or caused to be made a series of materially false or misleading statements about Alkermes' business, prospects and operations. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of Alkermes and its



business, prospects and operations, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Plaintiff and the other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

### **SCIENTER**

98. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Alkermes, their control over, and/or receipt of information of Alkermes' allegedly materially misleading misstatements and/or their associations with the Company that made them privy to confidential proprietary information concerning Alkermes, participated in the fraudulent scheme alleged.

### **Applicability Of Presumption Of Reliance: Fraud-On-The-Market Doctrine**

99. At all relevant times, the market for Alkermes' securities was an efficient market for the following reasons, among others:

(a) Alkermes' stock met the requirements for listing, and was listed and actively traded on the Nasdaq, a highly efficient and automated market;

(b) As a regulated issuer, Alkermes filed periodic public reports with the SEC; and

(c) Alkermes regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.

100. As a result of the foregoing, the market for Alkermes' securities promptly digested current information regarding Alkermes from all publicly available sources and reflected such information in Alkermes' stock price. Under these circumstances, all purchasers of Alkermes' securities during the Class Period suffered similar injury through their purchase of Alkermes' securities at artificially inflated prices and a presumption of reliance applies.

#### **NO SAFE HARBOR**

101. The statutory safe harbor provision for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the

forward-looking statement was authorized and/or approved by an executive officer of Alkermes who knew that those statements were false when made.

**COUNT I**

**Violation Of Section 10(b) Of  
The Exchange Act Against And Rule 10b-5  
Promulgated Thereunder Against All Defendants**

102. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

103. Throughout the Class Period, Alkermes and the Individual Defendants, carried out a plan, scheme, and course of conduct that was intended to and did: (i) deceive the investing public, including Plaintiff and the other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Alkermes' securities; and (iii) cause Plaintiff and the other members of the Class to purchase Alkermes' securities at artificially inflated prices. In furtherance of this unlawful scheme and course of conduct, Defendants took the actions set forth herein.

104. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Alkermes' securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

105. In addition to the duties of full disclosure imposed on Defendants as a result of their making of affirmative statements and reports, or participation in the making of affirmative statements and reports to the investing public, Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X (17 C.F.R. §§ 210.01 et seq.) and Regulation S-K (17 C.F.R. §§ 229.10 et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations, financial condition, and earnings so that the market price of the Company's securities would be based on truthful, complete, and accurate information.

106. Alkermes and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations, and future prospects of Alkermes as specified herein.

107. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Alkermes' value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Alkermes and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of Alkermes' securities during the Class Period.

108. The Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period; (ii) the Individual Defendants were privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; and (iii) the Individual Defendants were aware of the Company's dissemination of information to the investing public that they knew or recklessly disregarded was materially false and misleading.

109. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Alkermes' operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

110. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Alkermes' securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Alkermes' publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities

trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Alkermes securities during the Class Period at artificially high prices and were damaged thereby.

111. At the time of said misrepresentations and omissions, Plaintiff and the other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known of the true financial condition and business prospects of Alkermes, which were not disclosed by Defendants, Plaintiff and the other members of the Class would not have purchased or otherwise acquired their Alkermes securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices that they paid.

112. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

113. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

## **COUNT II**

### **Violation Of Section 20(a) Of The Exchange Act Against the Individual Defendants**

114. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

115. The Individual Defendants acted as controlling persons of Alkermes within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

116. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

117. As set forth above, Alkermes and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions, as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Alkermes' and the Individual Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.



**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff prays for relief and judgment, as follows:

- A. Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;
- B. Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;  
Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- C. Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: December 8, 2003

By his attorneys,

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**CERTIFICATION OF NAMED PLAINTIFF  
PURSUANT TO FEDERAL SECURITIES LAWS**

I, JAMES P. SLAVAS ("Plaintiff"), declare the following as to the claims asserted under the federal securities laws:

1. Plaintiff has reviewed the complaint filed in this matter and has authorized the filing of a complaint based on similar allegations in a related or amended complaint. Plaintiff retains Bernstein Liebhard & Lifshitz, LLP and such co-counsel it deems appropriate to associate with to pursue such action on a contingent fee basis.
2. Plaintiff did not purchase the security that is the subject of this action at the direction of Plaintiff's counsel or in order to participate in this private action.
3. Plaintiff is willing to serve as a lead plaintiff either individually or as part of a group. A lead plaintiff is a representative party who acts on behalf of other class members in directing the action, and whose duties may include testifying at deposition and trial. I understand that the litigation is not settled, this is not a claim form, and sharing in any recovery is not dependent upon execution of this Certification.

4. Plaintiff's transaction(s) in the ALKERMES, INC. security that is the subject of this action during the period of 4/22/99 through and including 7/1/02 are as follows:

<u>No. of Shares</u>	<u>Stock Symbol</u>	<u>Buy/Sell</u>	<u>Date</u>	<u>Price Per Share</u>
<u>100</u>	<u>ALKS</u>	<u>Buy</u>	<u>10/20/2000</u>	<u>39 3/16</u>

Please list other transactions on a separate sheet of paper, if necessary.

5. During the three years prior to the date of this Certification, Plaintiff has not sought to serve or served as a representative party for the class in any action filed under the federal securities laws except as indicated here:

6. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, or as ordered or approved by the court, including any award for reasonable costs and expenses (including lost wages) directly relating to the representation of the class.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 25 day of Nov, 2003.

Signature

Print Name

JAMES P. SLAVAS